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**MAIL STOP RCE**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: C.F. Ivory et al. Attorney Docket No.: WSUR117329  
Application No.: 09/885,439 Group Art Unit: 1743  
Filed: June 19, 2001 Examiner: J.T. Barton  
Title: **DEVICE AND METHOD FOR FOCUSING SOLUTES IN AN ELECTRIC  
FIELD GRADIENT**

**AMENDMENT AND RESPONSE TO FINAL EXAMINER'S ACTION**

Seattle, Washington 98101

June 23, 2005

**TO THE COMMISSIONER FOR PATENTS:**

**INTRODUCTORY COMMENTS**

In response to the Examiner's Action mailed March 10, 2005, please amend the above-identified application as indicated below.

Adjustment Date: 09/21/2005 SDIRETA1  
07/05/2005 VSEAFORT 00000002 031740 09885439  
01 FC:2201 100.00 CR

*file processed*

07/05/2005 VSEAFORT 00000002 09885439  
01 FC:2201 100.00 DA

07/05/2005 VSEAFORT 00000002 09885439  
01 FC:2201 100.00 CR

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MAIL STOP 16

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: C.F. Ivory et al.

Attorney Docket No.: WSUR1732910-2

Application No.: 09/885,439

Group Art Unit: 1743

Filed: June 19, 2001

Examiner: J.T. Burton

Title: DEVICE AND METHOD FOR FOCUSING  
SOLUTES IN AN ELECTRIC FIELD GRADIENT

US PATENT & TRADEMARK  
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REQUEST FOR REFUND  
(IMPROPER CHARGE OF DEPOSIT ACCOUNT)

Seattle, Washington 98101

July 28, 2005

DIRECTOR - U.S. PATENT AND TRADEMARK OFFICE:  
ATTENTION: Refund Section, Accounting Division, Office of Finance

I. Refund Request

This is a request for refund with respect to the charge to Deposit Account No. 03-1740, shown on the statement dated July 2005, for the above-identified patent application. A copy of the monthly statement, in which the error referred to occurs, accompanies this request.

II. Fees Charged for Which Refund Requested

Excess Claims

Amount of Fee Requested

\$100.00

Total Refund Requested:

\$100.00

III. Explanation of Why Contested Charge Is in Error

The \$100 fee for one additional independent claim was paid on June 23, 2005, with the filing of the Request for Continued Examination (RCE). Copies of the RCE, the Amendment and Response to Final Examiner's Action, the cancelled check, and the returned postcard are attached.

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IV. Manner of Refund

Please make refund by crediting Deposit Account No. 03-1740.

Respectfully submitted,

CHRISTENSEN O'CONNOR  
JOHNSON KINDNESS<sup>PLLC</sup>

*George E. Renzoni*

George E. Renzoni, Ph.D.  
Registration No. 37,919  
Direct Dial No. 206.695.1755

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Date:

*July 28, 2005*

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## Deposit Account Statement

Requested Statement Month: July 2005  
 Deposit Account Number: 031740  
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 Attention:  
 Address: 2800 PACIFIC FIRST CENTRE  
 City: SEATTLE  
 State: WA  
 Zip: 98101  
 Country: UNITED STATES OF AMERICA

DATE	SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
07/01	38	78661780	LANM232591	7001	\$650.00	\$2,70
07/01	46	E-REPLENISHMENT		9203	-\$5,000.00	\$7,70
07/01	63	78661793	LANM232590	7001	\$650.00	\$7,05
07/01	94	1869586	EUMA-2-31984	6214	\$200.00	\$6,8500DP/EEF
07/01	948	10485008	ROSA122230	8021	\$40.00	\$6,81
07/05	2	5702919	FHSP-1-7718	9204	-\$1,150.00	\$7,960 DKS
07/05	2	09885439	WSUR117329	2201	\$100.00	\$7,860 KBB
07/05	3	10952556	LEPA123665	1201	\$400.00	\$7,460 JEN/JLI
07/05	3	09885439	WSUR117329	1806	\$180.00	\$7,28
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07/05	324	2891614	28200 NOAM-2-28198/28200/7074/+	8503	\$15.00	\$7,13
07/05	325	1704302	7074 NOAM-2-28198/28200/7074/+	8503	\$15.00	\$7,11
07/05	326	2914836	28330 NOAM-2-28198/28200/7074/+	8503	\$15.00	\$7,10
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07/06	1	09885439	WSUR117329	1806	-\$180.00	\$7,13
07/06	154	11097975	UWOTL-1-24880	8021	\$40.00	\$7,09
07/06	488	76364678	HRCF-2-27867	7004	\$300.00	\$6,79
07/06	813	2215805	ATPI-2-16640 DIGP-16640	7205	\$100.00	\$6,69
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07/06	815	2215805	ATPI-2-16640 DIGP-16640	7206	\$100.00	\$6,39
07/06	1743	78664543	AWAP232756	7001	\$325.00	\$6,06
07/07	2	10038206	UOCB-1-18456	9204	-\$500.00	\$6,56
07/07	9	60677207	VANS124848	8021	\$40.00	\$6,52

MAIL STOP RCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: C.F. Ivory et al. Attorney Docket No.: WSUR117329  
Application No.: 09/885,439 Group Art Unit: 1743  
Filed: June 19, 2001 Examiner: J.T. Barton  
Title: DEVICE AND METHOD FOR FOCUSING SOLUTES IN AN ELECTRIC  
FIELD GRADIENT

REQUEST FOR CONTINUED EXAMINATION (RCE) UNDER 37 C.F.R. § 1.114 /  
PETITION FOR AN EXTENSION OF TIME UNDER 37 C.F.R. § 1.136(a)

Seattle, Washington 98101

June 23, 2005

TO THE COMMISSIONER FOR PATENTS:

This is a request for continued examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application, in which prosecution is closed.

- X 1. A submission as required under 37 C.F.R. § 1.114 is submitted as follows:
- X An Amendment/Response is enclosed herewith.
- X 2. Other documents enclosed are as follows:
- X a. Declaration of Dr. C.F. Ivory (Attachment A).
- X b. Curriculum Vitae (Attachment B).
- X c. Summary Statement (Attachment C).
- X d. Supplemental Information Disclosure Statement.
- X e. Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent. The enclosed check includes the statutory disclaimer fee of \$65.00.
- X 3. Small entity status is as follows
- X Small entity status was previously asserted and continues to be appropriate.

- X 4. Applicants respectfully request that the shortened statutory period for response to the final Office Action, dated March 1, 2005, set to expire on June 1, 2005, be extended by 1 month, to expire on July 1, 2005. The enclosed check includes the 1-month extension fee of \$60.00.
- X 5. The filing fee for the present request for continued examination is calculated below.
- X The enclosed amendment adds claims in excess of the number previously paid for. The claim fees are calculated as shown.

COMPUTATION OF FEE						
	Number Filed After Any Amendment	Highest Number Previously Paid For	Present Extra	Rate	Additional Fee	
Basic RCE Filing Fee	-	-	=	x	=	395
Total Claims	23	69	=	0	x	25 = 0
Independent Claims	8	7	=	1	x	100 = 100
Extension of Time				+	60	60
TOTAL						\$555

- X 6. Check No. 164424 in the amount of \$620.00, as computed above, is enclosed in payment of the required fees for filing the present request for continued examination.
- X 7. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17, and 1.18 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this request is enclosed.

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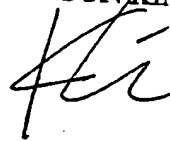
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Respectfully submitted,

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Date: 6/23/05

Carole Jolyan

KBB:cj

MAIL STOP RCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: C.F. Ivory et al.

Attorney Docket No.: WSUR117329

Application No.: 09/885,439

Group Art Unit: 1743

Filed: June 19, 2001

Examiner: J.T. Barton

Title: DEVICE AND METHOD FOR FOCUSING SOLUTES IN AN ELECTRIC  
FIELD GRADIENT

AMENDMENT AND RESPONSE TO FINAL EXAMINER'S ACTION

Seattle, Washington 98101

June 23, 2005

TO THE COMMISSIONER FOR PATENTS:

INTRODUCTORY COMMENTS

In response to the Examiner's Action mailed March 10, 2005, please amend the above-identified application as indicated below.



### AMENDMENTS TO THE CLAIMS

1. (Currently amended) A device for focusing a charged solute comprising:  
a first chamber for receiving a fluid medium, the first chamber having an inlet for introducing a first liquid to the chamber and an outlet for exiting the first liquid from the chamber;  
a second chamber comprising an electrode array, the second chamber having an inlet for introducing a second liquid to the chamber and an outlet for exiting the second liquid from the chamber;  
a porous material separating the first and second chambers; and  
means for dynamically controlling the voltage applied to the electrode array to produce a dynamically shaped local field.
2. (Original) The device of Claim 1 wherein the first and second chambers are in liquid communication when the chambers are filled with liquid.
3. (Original) The device of Claim 1 wherein the first chamber is in electrical communication with the electrode array when the chambers are filled with a conductive liquid.
4. (Original) The device of Claim 1 wherein the electrode array comprises a plurality of electrodes arranged linearly along the chamber length.
5. (Original) The device of Claim 4 wherein each electrode is individually controlled.
- 6-7. (Canceled)
8. (Original) The device of Claim 1 wherein the electrode array generates an electric field gradient profile.
- 9-16. (Canceled)

17. (Original) The device of Claim 1 further comprising a first conduit for introducing fluid media into the first chamber and a second conduit for exiting fluid media from the first chamber.

18-46. (Canceled)

47. (Currently amended) A method for focusing a charged solute in a fluid medium comprising:

introducing a charged solute into a fluid medium, wherein the fluid medium is contained in a device comprising:

a first chamber for receiving the fluid medium, the first chamber having an inlet for introducing a first liquid to the chamber and an outlet for exiting the first liquid from the chamber;

a second chamber comprising an electrode array, the second chamber having an inlet for introducing a second liquid to the chamber and an outlet for exiting the second liquid from the chamber;

a porous material separating the first and second chambers; and

means for dynamically controlling the voltage applied to the electrode array to produce a dynamically shaped field; and

applying an electric field gradient to the charged solute in the fluid medium to cause the charged solute to focus in a region of the medium.

48. (Original) The method of Claim 47 wherein the first liquid is an eluant buffer.

49. (Original) The method of Claim 47 wherein the second liquid is a coolant buffer.

50. (Original) The method of Claim 47 wherein the first liquid is the same as the second liquid.

51. (Original) The method of Claim 47 wherein the first liquid is different from the second liquid.

52-57. (Canceled)

58. (Currently amended) ~~The method of Claim 57~~ A method for focusing a charged solute comprising:

applying a charged solute to a fluid medium;  
applying a hydrodynamic force to the solute in the fluid medium; and  
opposing the hydrodynamic force with an electric field gradient to provide a solute focused in the fluid medium, wherein the electric field gradient is generated by an electrode array, wherein the electric field gradient is dynamically controlled to produce a dynamically shaped field, and wherein the electrode array comprises a plurality of electrodes arranged linearly along an axis parallel to direction of migration of the charged solute in the fluid medium.

59-62. (Canceled)

63. (Currently amended) ~~The method of Claim 57~~ A method for focusing a charged solute comprising:

applying a charged solute to a fluid medium;  
applying a hydrodynamic force to the solute in the fluid medium; and  
opposing the hydrodynamic force with an electric field gradient to provide a solute focused in the fluid medium, wherein the electric field gradient is generated by an electrode array, wherein the electric field gradient is dynamically controlled to produce a dynamically shaped field, and wherein the charged solute comprises a biological solute selected from the group consisting of a protein, peptide, oligonucleotide, polynucleotide, and mixtures thereof.

64-68. (Canceled)

69. (Currently amended) ~~The method of Claim 64~~ A method for separating charged solutes comprising:

applying a mixture of charged solutes to a fluid medium;  
applying a hydrodynamic force to the solutes in the fluid medium; and  
opposing the hydrodynamic force with an electric field gradient to separate the charged solutes in order of their electrophoretic mobilities, wherein the electric field gradient is generated by an electrode array, wherein the electric field gradient is dynamically controlled to produce a dynamically shaped field, and wherein the charged solute comprises a biological solute selected from the group consisting of a protein, peptide, oligonucleotide, polynucleotide, and mixtures thereof.

70. (Currently amended) A device for focusing a charged solute comprising:  
a first chamber for receiving a fluid medium, the first chamber having an inlet for introducing a first liquid to the chamber and an outlet for exiting the first liquid from the chamber;

a second chamber comprising an electrode array, the second chamber having an inlet for introducing a second liquid to the chamber and an outlet for exiting the second liquid from the chamber, wherein the electrode array is two-dimensional; and

a porous material separating the first and second chambers; and  
means for dynamically controlling the voltage applied to the electrode array to produce a dynamically shaped field.

71. (Currently amended) A method for focusing a charged solute in a fluid medium comprising:

introducing a charged solute into a fluid medium, wherein the fluid medium is contained in a device comprising:

a first chamber for receiving the fluid medium, the first chamber having an inlet for introducing a first liquid to the chamber and an outlet for exiting the first liquid from the chamber;

a second chamber comprising an electrode array, the second chamber having an inlet for introducing a second liquid to the chamber and an outlet for exiting the second liquid from the chamber, wherein the electrode array is two-dimensional; and

a porous material separating the first and second chambers; and

means for dynamically controlling the voltage applied to the electrode array to produce a dynamically shaped field;

applying an electric field gradient to the charged solute in the fluid medium to cause the charged solute to focus in a region of the medium.

72. (Previously presented) A system for focusing a solute, comprising:

a device, comprising:

a first chamber for receiving the fluid medium, the first chamber having an inlet for introducing a first liquid to the chamber and an outlet for exiting the first liquid from the chamber;

a second chamber comprising an electrode array, the second chamber having an inlet for introducing a second liquid to the chamber and an outlet for exiting the second liquid from the chamber; and

a porous material separating the first and second chambers;

a controller, comprising a plurality of controller units, wherein the plurality of controller units is in electrical communication with the electrode array;

at least one analytical instrument; and

an interface intermediate the device and the analytical instrument.

73. (Previously presented) The system of Claim 72, wherein the device further comprises:

at least a third chamber comprising at least a second electrode array, the at least a third chamber having an inlet for introducing at least a second liquid to the chamber and an outlet for exiting the at least a second liquid from the chamber, wherein the at least a second electrode array comprises a plurality of electrodes; and

at least a second porous material separating the first and at least a third chambers, wherein the first porous material and the at least a second porous material are on opposite sides of the first chamber, and the electrodes in the at least a second electrode array form pairs with the electrodes in the first electrode array.

74. (Previously presented) The device of Claim 72, wherein the controller dynamically monitors and sets the voltage at each electrode in response to signals from an operator.

75. (Previously presented) The device of Claim 72, wherein the controller dynamically monitors and sets the voltage at each electrode in response to signals from the at least one analytical instrument.

76. (Previously presented) The device of Claim 72, wherein the at least one analytical instrument comprises at least one of an optical detection device and a potentiometric detection device.

77. (Previously presented) The device of Claim 72, wherein the at least one analytical instrument comprises a video camera.

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### REMARKS

Claims 1-5, 8, 17, 47-51, 58, 63, and 69-77 are pending in the application and have been examined. Claims 1-5, 8, 17, 47-51, 57, 63, and 69-77 stand rejected. Claims 1, 47, 58, 63, 69, 70, and 71 have been amended. No new matter has been introduced. Reconsideration and allowance of Claims 1-5, 8, 17, 47-51, 58, 63, and 69-77 are respectfully requested.

#### 1. The Claim Objections

The Examiner has objected to Claims 58, 63, and 69 for depending from a canceled claim. The Examiner notes that Claims 58 and 63 were treated as incorporating all the limitations of canceled Claim 57, and Claim 69 was treated as incorporating all the limitations of canceled Claim 64. Claims 58 and 63 have been amended to incorporate all the limitations of canceled Claim 57, and Claim 69 has been amended to incorporate all the limitations of canceled Claim 64. Withdrawal of this ground of objection is respectfully requested.

#### 2. The Rejection Under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-3, 8, 17, 47-51, 63, and 69-71 under 35 U.S.C. § 102(b) as being anticipated by Koegler et al. (1996) *Biotechnol. Prog.* 12(6):822-36. According to the Examiner, no skilled or precise shaping is required by the claim language, and the general limitation "dynamic control" is met by any modification in the field in the course of the separation. Moreover, the Examiner states that the object of the limitation "dynamic control" is not to produce a dynamically shaped field. Applicants respectfully disagree.

As defined in the specification, dynamic control refers to controlling each electrode of the array individually to maintain and adjust the electric field gradient during the course of solute focusing and/or separation (Specification, page 8, lines 14-16). However, to more clearly define the claimed invention, independent Claims 1, 47, 58, 63, 69, 70, and 71, from which the Claims 2, 3, 8, 17, and 8-51 depend, have been amended to recite that the voltage applied to the

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electrode array or the electric field gradient is dynamically controlled to produce a dynamically shaped field. Support for this amendment can be found throughout the specification, for example, at page 4, lines 6-26; page 7, lines 8-15; page 21, lines 15-22; page 24, lines 13-19; page 25, lines 6-10). Applicants respectfully submit that Koegler et al. does not provide an enabling disclosure of means for dynamically controlling an electric field gradient to produce a dynamically shaped field.

For the reasons described above and the reasons provided in the Amendment and Response to the non-final Examiner's Action, filed January 3, 2005, Koegler et al. does not anticipate the claimed invention. Applicants respectfully request withdrawal of this ground of rejection.

### 3. The Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 4, 5, 58, 72, 74, and 76 under 35 U.S.C. § 103(a) as being obvious over Koegler et al. (1996) *Biotechnol. Prog.* 12(6):822-36 in view of U.S. Patent No. 5,298,143 (Ivory et al.). In addition, the Examiner has rejected Claims 73, 75, and 77 under 35 U.S.C. § 103(a) as being obvious over Koegler et al. in view of Ivory et al. as applied to Claim 72, and in further view of U.S. Patent No. 4,670,119 (Hurd), U.S. Patent No. 6,013,168 (Arai), or U.S. Patent No. 5,582,701 (Cabilly et al.), respectively. According to the Examiner, it would have been obvious to modify the device and method of Koegler et al. by using the linear array of electrodes and the controller comprising a plurality of controller units in communication with the electrode array disclosed in Ivory et al. Applicants respectfully disagree.

According to the Examiner, it is not apparent that the use of the array of electrodes disclosed in Ivory et al. in the device of Koegler et al. would result in severe peak smearing, as argued by the applicants in the Amendment and Response to the non-final Examiner's Action, filed January 3, 2005. Appended hereto as Attachment A is the declaration by Dr. C. F. Ivory

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("Ivory Declaration"), which explains that one of skill in the art would not have combined the array of electrodes disclosed in Ivory et al. with the device of Koegler et al., for the following reasons. One skilled in the art would have realized that the use of a linear electrode array as disclosed in Ivory et al. with the Koegler et al. device would have resulted in severe peak smearing, for the following reason: The large diameter of the dialysis tubing used in Koegler et al. (6 mm diameter, see Koegler et al., page 828, Column 2, first paragraph in "Experimental Results") would cause the proteins to be radially pulled away from the center of the dialysis tube to form a thin layer against the wall of the dialysis tube, which would then smear out perpendicularly (Ivory Declaration, paragraph 5). This smearing could be reduced but not eliminated by the use of a set of ring electrodes (Ivory Declaration, paragraph 5). Dialysis tubing with smaller diameters were not available at the time of publication of Koegler et al. Therefore, one of skill in the art would not have been motivated to combine any of the electrode arrays of Ivory et al. with the device of Koegler et al. to produce a dynamically shaped field (Ivory Declaration, paragraph 5).

In addition, there is objective evidence of non-obviousness of the claimed invention. After the time of publication of the Koegler et al. article, others in the field were skeptical that dynamic field gradient focusing would work (Ivory Declaration, paragraph 6). Moreover, others have copied and are using the claimed device, as described in the Ivory Declaration (Ivory Declaration, paragraph 7).

For the above reasons, and the reasons provided in the Amendment and Response to the non-final Examiner's Action, filed January 3, 2005, the cited references, either alone or in combination, fail to teach, suggest, provide any motivation to make, or otherwise render obvious the claimed invention. Withdrawal of this ground of rejection is respectfully requested.

#### 4. The Obviousness-Type Double Patenting Rejection

The Examiner has rejected Claims 1-5, 8, 17, and 70 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 7-12 and 21 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. In addition, the Examiner has rejected Claims 47-51 and Claim 58 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 32-36 and Claim 37, respectively, of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. The Examiner has also rejected Claims 72, 74, and 76 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. Furthermore, the Examiner has rejected Claims 63 and 69 under the doctrine of obviousness-type double patenting as being unpatentable over Claims 38 and 42 in view of Claim 25 of U.S. Patent No. 6,277,258. Moreover, the Examiner has rejected Claim 71 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 32 of U.S. Patent No. 6,277,258. Also, the Examiner has rejected Claims 72, 74, and 76 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. Finally, the Examiner has rejected Claims 73, 75, and 77 under the doctrine of obviousness-type double patenting as being unpatentable over Claim 7 of U.S. Patent No. 6,277,258 in view of Ivory et al. or Koegler et al. and in further view of Hurd, Arai, and Cabilly et al., respectively. A terminal disclaimer over U.S. Patent No. 6,277,258 is enclosed with this response. Withdrawal of this ground of rejection is respectfully requested.

#### Conclusion

In view of the above amendments and foregoing remarks, applicants believe that Claims 1-5, 8, 17, 47-51, 58, 63, and 69-77 are in condition for allowance. If any issues remain

that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at 206.695.1783.

Respectfully submitted,

CHRISTENSEN O'CONNOR  
JOHNSON KINDNESS<sup>PLLC</sup>



Karen Blöchlinger, Ph.D.  
Registration No. 41,395  
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36650  
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⑈ 03100000114 ⑈  
HACHVIA NA SVC871 27301  
PHILA, PA 06202005

05500228402

721534403

File No.: WSUR-1-17329

Appln. No.: 09/885,439

Atty/Secy: KBB/cj

Applicant(s): C.F. Ivory et al.

Title: DEVICE AND METHOD FOR FOCUSING SOLUTES IN AN ELECTRIC FIELD GRADIENT

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Request for RCE w/Ext. of Time (3 pages) in duplicate

Amendment/Response (12 pages)

Supplemental Information Disclosure Statement (2 pages) and 8 references

Declaration of Dr. C.F. Ivory (Attachment A) (3 pages)

Curriculum Vitae (Attachment B) (14 pages)

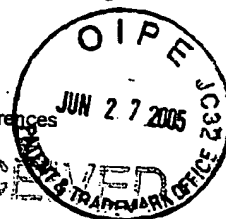
Summary Statement (Attachment C) (8 pages)

Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent (2 pages)

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